# Huayi Pharma

## Welcome to Huayi Pharmaceuticals



Huayi Pharmaceutical (Anhui) Co., Ltd.

Professional CDMO for high-quality generics

Based in Hefei, Eastern China







Huayi Pharmaceuticals was established in 2006 as a Sino-British joint venture between a UK-based generic company and a Chinese fine chemical supplier. Our goal was to create an independent export-oriented Chinese manufacturer, with the ambition of becoming the leading independent Chinese medicine supplier for customers in the European Union as well as Chinese customers.

Our facilities have passed several re-inspections by the MHRA since we were granted our EU Good Manufacturing Practice (GMP) Certificate in 2010 by the UK Medicines and Healthcare Regulatory Agency (MHRA). We continue to adhere to cGMP standards according to China and EU GMP requirements.

We can take your product through our pharmaceutical development process, with an expert quality management team to ensure your R&D project is completed on time and to the highest possible standards. To date, we are proud to have successfully transferred over 50 different products for our customers and have registered almost 100 strengths of product in the EU. From contract development, we can seamlessly scale-up to commercial manufacture and packaging, with serialisation lines fully implemented.

We will strive to provide quality service and faultless communication with our European customers. Through many years of close partnerships, we are confident that we can work effectively with new customers regardless of differences in our native languages and cultural backgrounds. We take pride in upholding our company values of quality, integrity and service in all of our interactions and projects



#### - Serving a little better everyday.

We want to provide the best service to our customers, ensure continued uninterrupted supply of medicines to patients and manufacture high-quality medicines at a reduced cost.

## **Our Principles**

## — Customer-focused service

We aim to provide excellent service to our customers and partners.

#### Cost-effective supply

We believe we can offer you significant cost-savings when developing and manufacturing your product in China. This does not mean that we are compromising in any aspect of our manufacturing, but we will negotiate the best possible prices for you, delivering your products to you on time and in full.

## —Responsive and communicative

We work to overcome language barriers and cultural differences in our working relationships.



## Huayi Pharmaceuticals

Committed to high-quality manufacturing
Dedicated to customer-focused service
Responsible for our patients, partners and
employees
Descriptions in projective thinking and excellence

Prioritising innovative thinking and excellence



## 专业专注·生产高水平仿制药

Dedicated to making high-quality generic medicines







## Quality

We are dedicated to maintaining the highest standards of manufacturing and producing high-quality medicines.



#### Integrity

We hold ourselves to a high standard of accountability.





#### Service

Our business is about supply and we should deliver our products and services in full, on time, every time



#### Resourcefulness

We prioritise good decision-making and seek to overcome challenges with new ideas.



#### Hello, Let us introduce Huayi Pharmaceuticals

## **Professional CDMO**





Huayi Pharmaceuticals is a contract development and manufacturing organisation (CDMO). Our facilities are based in China, serving customers from all over Europe. We are fully certified to manufacture in China and Europe and are familiar with the EU regulatory process, allowing us to produce dossiers that can be filed in both China and in the EU. We manufature solid oral dosage generic medicines in many different forms, including tablets (film-coated, sugar-coated, enteric-coated, effervescent, soluble, chewable, buccal) and capsules filled with powders or pellets.

We are confident in our ability to offer you cost-effective solutions whether it comes to contract development or contract manufacturing. While we offer significant cost-savings on your product, we will always ensure that what we manufacture is made in full, sent out on time and is of high-quality.

Our in-house team is made up of technical and regulatory experts, with rich expertise in project management. also have access to specialist technical consultants throughour innovative R&D department, the Huayi China-Europe Pharmaceutical Research Institute. Along with R&D and commercial production, we are also excited to offer integrated services that will allow our customers to conduct biological testing of their products in China.

Customers will also have access to our clinical trial facilities through our partner Weida Clinical Research. We feel that conducting the necessary bioequivalence studies in China would be very beneficial in terms of successfully registering the product within the country. Our ambition is to become a leading independent Chinese medicine supplier. We are committed to upgrading and developing our facilities to provide better services for our customers.

Our high-potency and liquid preparation workshop will be completed in 2020. We are eager to try new technologies, develop new products and manufacture for our customers to the highest quality possible.



## One Stop Solution for pharmaceutical development, contract manufacture, quality control





### Service Structure

Development - Quality - Manufacture - Packaging

Let our team at Huayi China-Europe Research Institute develop your next product. We have a complete project management system to ensure your product will be developed on time according to your specifications. Our R&D team have an independent GMP Development Workshop where we prepare our pilot and scale-up batches. Seamlessly scale-up your product from small batches to commercial production at our GMP-approved facilities. Our production capacity currently sits at 3 billion units. In 2018, we manufactured 1.3 billion tablets and 30 million capsules. Our capacity will be increased in the future in order to meet demand. Our packing lines have had serialisation and tamper-evident closures fully implemented. Our partners Velocyte and Weida Cliical Research provide an integrated service for any bioequivalence studies you might require.



#### Pharmaceutical Development

- 1. Preformulation
- 2. Formulation Development
- Tablets: sublingual, dispersible, effervescent
- 4. Capsules: hard gel, pellets





#### **Quality Management**

- 1. Clinical GMP supply
- 2. Commercial manufacture

#### **GMP** Development

Our GMP workshop is capable of manufacturing batch sizes from 10,000 up to 100,000 tablets for pilot batches, clinical trial batches and process validation batches





#### **Technology Transfer**

We have over 50 products are commercially manufactured for several European countries including some products developed from scratch by our R&D team.

#### **Integrated Services**

we are partnered with Weida Clinical Research(Hefei) Ltd.and Velocyte Analyticl Technology(Hefei) Co.,Ltd.to offer clinical trials and biological testing of samples.

#### Weida

Weida Clinical Research is run by an experienced clinical trials team and nurses. We are able to recruit participants from Hefei and our neighbouring provinces easily, due to our central geographic location.

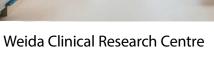




#### Velocyte

Bioequivalence studies can be completed in Velocyte, which is located in the same facility as the rest of Huayi. This ensures seamless communication between different departments.







Velocyte Bioequivalence Study Centre



Thank you for reading about Huayi Pharmaceuticals.

Let's make your project happen.



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